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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/530,817

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P-5856

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07/19/2010

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EXAMINER

SHELL, LAURA C

ART UNIT

PAPER NUMBER

3767

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/530,817	Applicant(s) ALHEIDT ET AL.	
	Examiner LAURA C. SCHELL	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-6 and 18-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-6, 18-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

In view of the Appeal Brief filed on 5/10/2010, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

/KEVIN C. SIRMONS/

Supervisory Patent Examiner, Art Unit 3767.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4-6, 22 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Greenwood (US Patent No. 5,120,314). Greenwood discloses the device substantially as claimed including an iv flush syringe assembly (this syringe is perfectly capable of being used for flushing an iv) comprising: a barrel (10) having an inside surface defining a chamber for retaining fluid, an open proximal end (near 15) and a distal end (near 13) including a distal wall with an elongate tip (wall 13, tip 21) extending distally therefrom having a passageway therethrough in fluid communication with said chamber, said inside surface integrally having a contact area at the distal end of the barrel (Figs. 1, 3 and 6 disclose that the contact area is the area 50 at the distal end of the barrel; it has been held that the term "integral" is sufficiently broad to embrace constructions united by such means as fastening and welding, therefore it can be said that the contact area provided by the ring 50 is integral with the inside surface), a plunger (30) including an elongate body portion (32) having a proximal end (near 35), a distal end (near 36) and a flexible stopper (40) slidably positioned in fluid tight engagement with said inside surface of said barrel for drawing fluid into and driving fluid out of said chamber by movement of said stopper relative to said barrel, said elongate body portion extending outwardly from said open proximal end of said barrel (Fig. 1); wherein said contact area has a higher coefficient of friction than said inside surface outside of said contact area for frictionally engaging said stopper when said stopper is in contact with said distal wall of said barrel for frictionally holding said stopper in a partially deflected position to prevent reflux of the fluid back into the chamber after fluid has been delivered from said chamber (Figs. 1-10 disclose that the inside surface of the

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barrel at area 50 has a portion with multiple tabs such as 67 in fig. 6 and 82 in Fig. 10, wherein the tabs are discontinuous with the inner surface of the barrel and therefore provide an area of higher coefficient of friction. The tabs engage with the plunger 42 as seen in Fig. 10, and col. 5, lines 39-45 disclose that the tabs "dig into the elastic piston 40" which therefore indicates that the digging in of the tabs partially deforms/deflects the piston, and this action keeps the piston at the distal end of the barrel preventing reflux of fluid), wherein the diameter of the outer surface of each portion of the stopper is less than or equal to the largest diameter of the inside surface of the distal end of the barrel having the contact area when the stopper is in the partially deflected position (Fig. 10 discloses that the outside diameter of 42 is equal to or less than the diameter of the interior surface of the barrel wall).

In reference to claim 5, Greenwood discloses that the contact area includes a plurality of annular deformations (the area above and below ring portion 64 in Fig. 6, for example, discloses at least 2 annular deformations).

In reference to claim 6, Greenwood discloses that the annular deformations are annular projections on said inside surfaces of said barrel (Figs. 1-10).

In reference to claim 22, Greenwood discloses that the stopper is made from rubber (col. 4, lines 57-58).

In reference to claim 23, Greenwood discloses that the stopper can be removed from said contact area after said stopper has contacted said distal wall of said barrel (if one were to use enough force, one could pull the stopper out of the barrel. The stopper may be damaged by doing this, but Applicant has not claimed such).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 4-6, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greenwood (US Patent No. 5,120,314). Greenwood discloses the device substantially as claimed including an iv flush syringe assembly (this syringe is perfectly capable of being used for flushing an iv) comprising: a barrel (10) having an inside surface defining a chamber for retaining fluid, an open proximal end (near 15) and a distal end (near 13) including a distal wall with an elongate tip (wall 13, tip 21) extending distally therefrom having a passageway therethrough in fluid communication with said chamber, said inside surface further including a contact area at the distal end of the barrel (Figs. 1, 3 and 6 disclose that the contact area is the area 50 at the distal end of the barrel), a plunger (30) including an elongate body portion (32) having a

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proximal end (near 35), a distal end (near 36) and a flexible stopper (40) slidably positioned in fluid tight engagement with said inside surface of said barrel for drawing fluid into and driving fluid out of said chamber by movement of said stopper relative to said barrel, said elongate body portion extending outwardly from said open proximal end of said barrel (Fig. 1); wherein said contact area has a higher coefficient of friction than said inside surface outside of said contact area for frictionally engaging said stopper when said stopper is in contact with said distal wall of said barrel for frictionally holding said stopper in a partially deflected position to prevent reflux of the fluid back into the chamber after fluid has been delivered from said chamber (Figs. 1-10 disclose that the inside surface of the barrel at area 50 has a portion with multiple tabs such as 67 in fig. 6 and 82 in Fig. 10, wherein the tabs are discontinuous with the inner surface of the barrel and therefore provide an area of higher coefficient of friction. The tabs engage with the plunger 42 as seen in Fig. 10, and col. 5, lines 39-45 disclose that the tabs "dig into the elastic piston 40" which therefore indicates that the digging in of the tabs partially deforms/deflects the piston, and this action keeps the piston at the distal end of the barrel preventing reflux of fluid), wherein the diameter of the outer surface of each portion of the stopper is less than or equal to the largest diameter of the inside surface of the distal end of the barrel having the contact area when the stopper is in the partially deflected position (Fig. 10 discloses that the outside diameter of 42 is equal to or less than the diameter of the interior surface of the barrel wall). As pointed out in the 102 rejection above, it is the examiner's position that the term "integral" is sufficiently broad to embrace constructions united by such means as fastening and welding, and

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therefore it is reasonable to conclude that Greenwood teaches a contact area integral with the inside surface of the barrel. However, even if Applicant argues that the contact area (50) taught by Greenwood is not integral, it would have been obvious to one having ordinary skill in the art at the time of the invention to have made the contact area (50) of Greenwood integral with the inside surface of the barrel in order to make sure that the contact area does not accidentally become dislodged/break away from the inside surface and therefore render the device's protection system useless, since it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art.

In reference to claim 5, Greenwood discloses that the contact area includes a plurality of annular deformations (the area above and below ring portion 64 in Fig. 6, for example, discloses at least 2 annular deformations).

In reference to claim 6, Greenwood discloses that the annular deformations are annular projections on said inside surfaces of said barrel (Figs. 1-10).

In reference to claim 22, Greenwood discloses that the stopper is made from rubber (col. 4, lines 57-58).

In reference to claim 23, Greenwood discloses that the stopper can be removed from said contact area after said stopper has contacted said distal wall of said barrel (if one were to use enough force, one could pull the stopper out of the barrel. The stopper may be damaged by doing this, but Applicant has not claimed such).

Claims 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greenwood (US Patent No. 5,120,314) in view of Lynn (US Patent No. 5,522,804). Greenwood discloses the device substantially as claimed except for a tip cap and flush solution. Lynn, however, discloses a flushing syringe (Figs. 13 and 7c) with a tip cap (Fig. 7c, 124) and flushing solution in the chamber of the syringe, wherein the flushing solution is saline (Fig. 7c, 130; Fig. 7c discloses that the syringe obtains the flush solution, saline (130) from the pouch by drawing it into the chamber area (seen in Fig. 7c as area 26), as better described by Col. 14, lines 20-30). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Greenwood with a cap and the use of saline solution, as taught by Lynn, in order to seal the end of the syringe and to provide the syringe with a flushing solution, since the syringe of Greenwood is structurally equivalent to a flushing syringe and is therefore perfectly capable of being used as a flushing syringe.

Response to Arguments

Applicant's arguments filed 5/10/2010 have been fully considered but they are not persuasive. In the Appeal Conference held regarding this application, it was decided that a 102 rejection under the Greenwood reference should have been made as the examiner had been interpreting "integrally" too narrowly, and that since Greenwood discloses that the contact area (50) is attached to the inside surface of the barrel it is still integral with the barrel. As further disclosed above, in the event that Applicant

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argues that contact area 50 is not integral with the barrel, a 103 rejection has also been provided, as it involves only routine skill in the art to form in one piece an article which has formerly been formed in two pieces.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA C. SCHELL whose telephone number is (571)272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Laura C Schell/

Examiner, Art Unit 3767

/KEVIN C. SIRMONS/

Supervisory Patent Examiner, Art Unit 3767